

REMARKS

A. BACKGROUND

The present Amendment is in response to the Office Action mailed February 3, 2009. Claims 1, 3-6, 21-28, and 31-42 were pending and rejected in view of cited art.¹ Claims 1, 4, 28, 31, 33-37, and 39 are amended. Claims 1, 3-6, 21-28, and 31-42 are now pending in view of the above amendments.²

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, are consistent with the Examiner's understanding.

B. CLAIM OBJECTIONS

The Examiner objected to claim 31 because of one or more informalities. Claim 31 has been amended to correct the informalities identified by the Examiner.

C. PRIOR ART REJECTIONS

I. REJECTION UNDER 35 U.S.C. § 103

The Office Action rejected claims 1, 3-6, 21-28, and 31-32 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Publication No. 2002/0082679 (*Sirhan*) in view of U.S. Patent No. 6,254,631 (*Thompson*) and further in view of U.S. Patent No. 6,174,329 (*Callol*). Claims 33-42 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Sirhan* in view of *Thompson*,

¹ Although the prior art status of the cited art is not being challenged at this time, Applicant reserves the right to challenge the prior art status of the cited art at any appropriate time, should the need arise. Accordingly, any arguments and amendments made herein should not be construed as acquiescing to any prior art status of the cited art.

² Support for the claim amendments and/or new claim(s) can be found throughout the specification and/or drawings as originally filed.

as applied *supra*, further in view of U.S. Patent No. 6,387,123 (*Jacobs*).

Applicant traverses the Examiner’s rejection for obviousness on the grounds that the references – either individually or in combination – fail to disclose, teach, or suggest each and every element of the rejected claims. As currently amended, claim 1 recites, in part, “a polymer-free external coating consisting of a therapeutic agent disposed directly on the exterior or interior surface of the stent.”

In direct contrast, however, *Sirhan* does not disclose, teach, or suggest this claim element. Rather, *Sirhan* teaches that after “[t]he drug was loaded onto the stent,” that the polymer “Parylene was then vacuum deposited on the stent to serve as a rate-controlling barrier.” (¶ 177.) Accordingly, *Sirhan* does not disclose, teach, or suggest “a polymer-free external coating consisting of a therapeutic agent disposed directly on the exterior or interior surface of the stent” as recited, in part, by claim 1.

The Office Action cites *Callol* as alternative support, which allegedly teaches “the use of sandblasting as a suitable means for roughening a stent surface.” (Office Action, 4.) Applicant respectfully traverses. *Callol* does not teach sandblasting a stent surface, but rather teaches sandblasting a “radiopaque layer” (or “substrate”) to “improv[e] adhesion between the protective layer and the radiopaque layer.” (See col. 7, ll. 23-27.) In addition, *Callol* teaches the use of a “protective layer” such as a “polymeric” coating and does not appear to teach the use of a therapeutic agent. Accordingly, *Callol* does not appear to remedy the deficiencies of *Sirhan* with respect to claim 1. Furthermore, *Jacobs* does not appear to remedy the deficiencies of *Sirhan* and *Callol* with respect to claim 1.

Similar to claim 1, claim 34 has been amended to recite, in part, “a polymer-free external coating disposed directly on at least a portion of the roughened and annealed exterior surface of the stent, the external coating comprising a therapeutic agent and forming the outermost peripheral surface of the stent system,” and claim 39 has been amended to recite, in part, “a polymer-free external coating disposed on and abutting at least a portion of the exterior surface and interior surface of the stent, the external coating comprising a therapeutic agent forming an outermost peripheral surface of the stent system at the at least a portion of the exterior surface and interior surface.” For at least the same reasons set forth above with respect to claim 1, Applicant respectfully submits that *Sirhan* does not disclose, teach, or suggest each and every element of claims 34 and 39 as presently claimed. In particular, *Sirhan* does not teach “a polymer-free external coating . . . forming the outermost peripheral surface of the stent system”

as recited, in part, by claim 34 and as similarly recited, in part, by claim 39. Rather, in direct contrast, *Sirhan* teaches an external coating consisting of Parylene, a polymer, which is "vacuum deposited on the stent to serve as a rate-controlling barrier." (§ 177.) In addition, neither *Callol* nor *Jacobs* appear to remedy the deficiencies of *Sirhan* with respect to claims 34 and 39.

In view of the failure of *Sirhan*, *Callol*, and *Jacobs* to disclose, teach, or suggest each and every element of claims 1, 34, and 39, Applicant submits that the Office Action fails to set forth a *prima facie* case for obviousness and respectfully requests that the rejection be withdrawn. The corresponding dependent claims are allowable for at least the same reasons claims 1, 34, and 39 are allowable.

In addition, as discussed above, both *Sirhan* and *Callol* teach away from the present claims. Unlike claims 1, 34, and 39, which recite, in part, "a polymer-free external coating," *Sirhan* teaches vacuum depositing Parylene, a polymer, onto the stent. (See § 177.) Meanwhile, *Callol* teaches that "a preferred method is to deposit Parylast®, a proprietary Parylene C coating," onto the stent. (See col. 7, ll. 19-21.) Since both *Sirhan* and *Callol* teach away from claims 1, 34, and 39, Applicant further submits that claims 1, 34, and 39 are not rendered obvious by *Sirhan* or *Callol*.

D. CONCLUSION

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

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For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 6th day of July, 2009.

Respectfully submitted,

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